Minute Order Form (06/97)

United States District Court, Northern District of Illinois

Name of Assigned Judge or Magistrate Judge	Ronald A.Guzman	Sitting Judge if Other than Assigned Judge	
CASE NUMBER	04 C 836	DATE	8/13/2004
CASE TITLE	Abbott Laboratories, et al. V. Baxter Healthcare Corp.		

[In the following box (a) indicate the party filing the motion, e.g., plaintiff, defendant, 3rd party plaintiff, and (b) state briefly the nature of the motion being presented.]

MOTION:

DOCKET ENTRY:

(1) ☐ Filed motion of [use listing in "Motion" box above.]

(2) ☐ Brief in support of motion due _____.

(3) ☐ Answer brief to motion due_____. Reply to answer brief due_____.

(4) ☐ Ruling/Hearing on _____ set for _____ at _____.

(5) ☐ Status hearing[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(6) ☐ Pretrial conference[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(7) ☐ Trial[set for/re-set for] on _____ at _____.

(8) ☐ [Bench/Jury trial] [Hearing] held/continued to _____ at _____.

(9) ☐ This case is dismissed [with/without] prejudice and without costs[by/agreement/pursuant to]
☐ FRCP4(m) ☐ Local Rule 41.1 ☐ FRCP41(a)(1) ☐ FRCP41(a)(2).

(10) ■ [Other docket entry] ENTER MEMORANDUM OPINION AND ORDER. For the foregoing reasons, the Court denies Defendant's motion to dismiss for lack of subject matter jurisdiction and denies Defendant's alternative motion to stay this case pending the outcome of case no. 01 C 1867 [doc. Nos. 9-1 and 9-2].

(11) ☐ [For further detail see order (on reverse side of/attached to) the original minute order.]

	No notices required, advised in open court.		number of notices	Document Number
	No notices required.		AUG 16 2004	
✓	Notices mailed by judge's staff.		date docketed	
	Notified counsel by telephone.		docketing deputy initials	20
	Docketing to mail notices.		8/13/2004	
	Mail AO 450 form.		date mailed notice	
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CG	courtroom deputy's initials	U.S. DISTRICT COURT 2004 AUG 13 PM 3:27 Date/time received in central Clerk's Office	CG mailing deputy initials	

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ABBOTT LABORATORIES, an Illinois Corporation, and CENTRAL GLASS COMPANY LTD. a Japanese Corporation,	)	
Plaintiffs,	)	**Judge Ronald A. Guzmán**
v.	)	**04 C 836**
BAXTER HEALTHCARE CORP., a Delaware Corporation,	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

Plaintiffs Abbott Laboratories and Central Glass Company Ltd. have sued Defendant Baxter Healthcare Corp. for alleged infringement of U.S. Patent No. 6,677,492 ("the '492 patent") and U.S. Patent No. 6,444,859 ("the '859 patent"). Defendant has moved to dismiss the complaint pursuant to Federal Rule of Civil Procedure ("Rule") 12(b)(1), or in the alternative, to stay this case pending the outcome of case no. 01 C 1867. For the reasons provided in this Memorandum Opinion and Order, the Court denies Defendant's motion to dismiss for lack of subject matter jurisdiction and denies Defendant's motion to stay.

FACTS

This complaint arises out of an Abbreviated New Drug Application ("ANDA") filed by Defendant in June 2000 seeking approval to sell generic sevoflurane in aluminum containers lined with an epoxyphenolic liner. Sevoflurane is a fluorine-based

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inhalation anesthetic first developed by Defendant in the mid-1960s. It is used as a general anesthesia for patients undergoing surgery and accounted for more than fifty percent of sales of all anesthetics capable of being inhaled in 2000. The original patent on sevoflurane has long since expired, and due to a complicated licensing agreement, Abbott Laboratories is the sole seller of sevoflurane in the United States. However, Abbott has several patents for inhibiting degradation of liquid sevoflurane by Lewis acids, which can result in harmful by-products. In order to prevent degradation, Abbott determined that a Lewis acid inhibitor (one of which is water) could be added to the sevoflurane. Abbott's U.S. Patent No. 5,990, 176 ("the '176 patent") teaches that to stop degradation, an effective stabilizing amount of Lewis acid inhibitor must be added to the sevoflurane. The '176 patent is at issue in pending case no. 01 C 1867, in which Abbott filed for infringement under the Hatch-Waxman Act.

This case stems from two separate patents - the '492 patent and the '859 patent. The '492 patent claims a method for storing sevoflurane in a container having an interior wall coated with a Lewis acid inhibitor. The '859 patent claims a method of preventing degradation of sevoflurane by using at least 150 parts per million of a Lewis acid inhibitor. Defendant's ANDA was approved on July 2, 2002 for a generic sevoflurane product with a water content of 130 parts per million or less, and the specification states that the generic sevoflurane will be sold in aluminum containers lined with an epoxyphenolic liner. The '492 patent was issued on January 13, 2004, and the '859 patent was issued on September 3, 2002. Plaintiff in this case seeks a declaratory judgment under 28 U.S.C. § 2201 that Defendant will infringe the '492 patent and the '859 patent in December 2005, the earliest that Defendant can market sevoflurane as a result of an

arbitral ruling, which was subsequently challenged by Defendant and upheld by this Court. *See Abbott Labs. v. Baxter Int'l, Inc.*, Nos. 01 C 4809, 01 C 4839, 2002 WL 467147, at *5-6 (N.D. Ill. Mar. 27, 2002), *aff'd*, 315 F.3d 829 (7th Cir. 2003), *cert. denied*, 124 S. Ct. 387 (2003). This case was filed on February 2, 2004, almost twenty-two months before Defendant would be able to market its generic product.

DISCUSSION

A defendant can move to dismiss under Rule 12(b)(1) by challenging the subject matter jurisdiction of the court based on the sufficiency of the allegations in the complaint (a facial attack), or by challenging the factual basis for subject matter jurisdiction (a factual attack). *Cedars-Sinai Med. Ctr. v. Watkins*, 11 F.3d 1573, 1583 (Fed. Cir. 1993). When a facial attack is made, the allegations in the complaint are accepted as true and all reasonable inferences are drawn in favor of the plaintiff. *Ezekiel v. Michel*, 66 F.3d 894, 897 (7th Cir. 1995). If the motion denies or contradicts the allegations of jurisdiction in the complaint, the movant is making a factual attack. *Cedars-Sinai*, 11 F.3d at 1583. When a factual attack is made, the court may look beyond the allegations in the complaint to determine whether subject matter jurisdiction exists. *Ezekiel*, 66 F.3d at 897.

Defendant launches a factual attack on jurisdiction because it argues that Plaintiffs' characterization of this case as reviewable by this Court under the Declaratory Judgment Act, 28 U.S.C. § 2201, is incorrect.

In the patent arena, potential infringers, to "clear the air of infringement charges," have historically used declaratory judgments under 28 U.S.C. § 2201 to declare that the

patent will not be infringed or that the patent itself is invalid. *Inamed Corp. v. Kuzmak*, 249 F.3d 1356, 1362 (Fed. Cir. 2001). However, patentees can also attempt to declare their rights under § 2201 against parties that will allegedly infringe in the future. *Lang v. Pacific Marine & Supply Co. Ltd.*, 895 F.2d 761, 763 (Fed. Cir. 1990). Under § 2201, an "actual controversy" must exist between the parties, and *Lang* outlines two elements required for a patentee against an alleged infringer to satisfy this requirement: 1) the alleged infringer "must be engaged in activity directed toward making, selling, or using . . . or be making meaningful preparation for such activity"; and (2) the alleged infringer "must indicate a refusal to change the course of its actions in the face of acts by the patentee sufficient to create a reasonable apprehension that a suit will be forthcoming." *Id.* at 764. The first element looks to the alleged infringer's conduct to determine whether the controversy is sufficiently real and substantial and has been labeled the "reality" element, while the second element requires that the controversy is of "sufficient immediacy" and has been labeled the "immediacy" element. *Id.*; *see Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104, 112 (D. Mass. 1998).

The "reality" element is met if the design of the potentially infringing product has been substantially fixed, especially the features that would potentially infringe, at the time the complaint was filed. *Sierra Applied Scis., Inc. v. Advanced Energy Indus., Inc.*, 363 F.3d 1361, 1379 (Fed. Cir. 2004). The greater the variability of a potentially infringing feature, the more likely the suit will be advisory and "detached from eventual reality." *Id.* For a decision to be anything other than an advisory opinion, it must be established "'that the product presented to the court is the same product which will be produced if a declaration of noninfringement is obtained.'" *Id.* (quoting *Int'l Harvester*

Co. v. Deere & Co., 623 F.2d 1207, 1216 (7th Cir. 1980)). Moreover, the possibility that the design of a product might change is not alone enough to defeat jurisdiction. *Lang*, 895 F.2d at 764; *Interdigital Tech. Corp. v. OKI Am., Inc.*, 845 F. Supp. 276, 284 (E.D. Penn. 1994).

Defendant contends that the "reality" element is not met because there is no guarantee that it will ultimately market a sevoflurane product in the United States, and even if it did market sevoflurane, the packaging may change between the filing of the complaint and December 2005, when it would be permitted to enter the market.

Defendant cites *Abbott Laboratories v. Zenith Laboratories, Inc.* ("*Zenith*") in support of its contention that it may not ultimately market sevoflurane in the United States. 934 F. Supp. 925 (N.D. Ill. 1995). In that case, the plaintiff was claiming that the defendant was taking action toward making, selling, or using of a generic form of HYTRIN because the defendant sought FDA approval to market generic HYTRIN. *Id.* at 937-38. However, the court specifically noted that FDA approval was not granted at the time declaratory judgment was requested, and there was no guarantee that FDA approval would be granted on any particular date in the future. *Id.* at 938. Accordingly, the court stated that a request for FDA approval does not necessarily mean that the defendant will not change its course of actions and decide against marketing the drug, thereby failing to meet the "reality" element of the *Lang* test. *Id.*

Zenith can be distinguished from our case because the Defendant Baxter had already received *approval* of its ANDA at the time that the complaint was filed. Plaintiffs cite *Glaxo Group Ltd. v. Apotex, Inc.* ("*Apotex*"), in which the district court stated that the filing of an ANDA for an antibiotic "means that defendant is ready or has

at least made meaningful preparations to be ready to market the allegedly infringing product." 130 F. Supp. 2d 1006, 1008 (N.D. Ill. 2001). In addition, the Federal Circuit in *Glaxo, Inc. v. Novopharm, Ltd.* ("*Novopharm*") noted that "systematically attempting to meet the applicable regulatory requirements" by filing an ANDA indicated an intent to enter the market. 110 F.3d 1562, 1571 (Fed. Cir. 1997). *Novopharm* also states that declaratory relief "is directed to the time after the ANDA is approved, when § 271(e)(1) no longer provides a shelter against infringement liability." *Id.* at 1571. *Apotex* and *Novopharm* both support the proposition that the *filing* of an ANDA indicates intent to enter the market, and *Novopharm* further indicates that the *approval* of an ANDA is sufficient to trigger an action for declaratory relief. *See also Amgen*, 3 F. Supp. 2d at 113 (noting that the issuance by the FDA of a product license would show good cause to reopen declaratory judgment claim); *Andrx Pharms. Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 808 (D.C. Cir. 2001) (indicating in an antitrust suit that a party "could have alleged its intent and preparedness to enter the market by claiming that FDA approval was probable" even without ANDA approval itself). Moreover, Defendant challenged the findings of an arbitration panel that would prevent entry into the market until December 2005, further evidence of its intent to enter the market. *Abbott Labs. v. Baxter Int'l, Inc.*, 2002 WL 467147, at *5-6.

Defendant suggests that even if it does enter the generic sevoflurane market, the packaging used may not be a lined container, and therefore the controversy would not meet the "reality" prong of the *Lang* test. To support this contention, Defendant cites *Telectronics Pacing Systems, Inc. v. Ventritex, Inc.* a case in which the Federal Circuit held that a defibrillator device that had only begun clinical trials did not satisfy the

"reality" requirement because there was no certainty that the device approved would be the same device being used for clinical trials. 982 F.2d 1520, 1527 (Fed. Cir. 1992). Venitrex, pursuant to an Investigational Device Exemption from the FDA, began clinical trials in July 1989 and sold defibrillator devices at cost in order to obtain data for pre-market FDA approval. *Id.* at 1521. Telectronics sought a declaratory judgment that Venitrex's activity would infringe Telectronic's patents when its clinical testing exception ended. *Id.* at 1522. The court found that the "reality" element was not met because the device sold could differ from the device used for clinical trials, the device did change during clinical trials, and Venitrex was prohibited by the FDA from distributing sales literature or seeking orders. *Id.* at 1527.

However, in our case, Defendant's ANDA has already been approved, which distinguishes this case from the defibrillator device in *Telectronics*, where the device was only in the clinical testing stage. The product is primed for the market per its approved ANDA. Defendant cannot contend that a product in the early stages of development can be readily compared to a product that is already approved for the market.

Defendant also cites *Sierra Applied Sciences, Inc. v. Advanced Energy Industries, Inc.*, a case in which the plaintiff could not prove that the design of the defendant's 150 kW power supply was substantially fixed, especially regarding its potentially infringing characteristics, at the time the complaint was filed. 363 F.3d at 1379-80. The power supply was in an early stage of development, and it would be potentially several years before the product would be available for sale, which could result in even more design changes. *Id.* at 1380.

Defendant errs in comparing product development of a power supply with that of

a generic drug, especially in light of the ANDA process. One purpose of the ANDA process and 35 U.S.C. § 271(e)(1) is to expedite the arrival of generic drugs on the market by protecting the limited use of patented drugs for development and submission to the FDA, which allows for the generic manufacturer to have regulatory approval before expiration of the patent. *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1272-73 (N.D. Cal. 1991). The *approved* ANDA is the final product that will be marketed when the patent expires (or in this particular case, in December 2005, per the arbitral award), and Defendant's approved ANDA includes packaging in a lined aluminum container.

Defendant states that it "intends to go to market on the sevoflurane product described in its current ANDA," but that there is "no guarantee that the packaging of that hypothetical product will not change between now and December 2005." (Def.'s Reply Mem. Supp. Mot. Dismiss at 5.) However, the court in *Lang* stated that a "concern that the alleged future infringer might alter its course of conduct or discontinue it altogether should not cause a dismissal any more than it should in a suit by the accused infringer." 895 F.2d at 764. Based on Defendant's approved ANDA, the product that will be marketed by Defendant is generic sevoflurane in a lined aluminum container. Even though it is not "guaranteed" that Defendant will use such packaging, failure to do so will require Defendant to amend its ANDA (especially in light of the potentially harmful degradation problems with sevoflurane), as packaging information is required when filing. *See* 21 C.F.R. § 314.94 (2004) (stating content requirements for ANDA include packaging requirements under pertinent provisions of 21 C.F.R. § 314.50(d)). Indeed, had Defendant not been prevented from entering the market as a result of an arbitration

award (which Defendant attempted but failed to vacate), it is hard to believe that Defendant would not currently be producing generic sevoflurane (utilizing the sevoflurane manufacturing line which it has in place) in lined containers per its approved ANDA. The Court is guided by the Federal Circuit decision in *Sierra*, because given a finding of noninfringement in this case the product introduced to the Court is most likely the same product that would be marketed by the Defendant. *See* 363 F.3d at 1379 (quoting *Int'l Harvester*, 623 F.2d at 1216) (noting that for a decision to be anything other than an advisory opinion, it must be established "'that the product presented to the court is the same product which will be produced if a declaration of noninfringement is obtained.'") Because Defendant is likely to market generic sevoflurane in December 2005, and likely as well to use a lined aluminum container, the "reality" element of the *Lang* test is met in this case. If Defendant amends its ANDA filing to change packaging, eliminating the container lined with a potential Lewis acid inhibitor that could potentially infringe the '492 patent, then this case would most likely become nonjusticiable, as the "reality" prong would not be met. *See Abbott Labs. v. Baxter Pharm. Prods., Inc.*, No. 00 C 5939, 2002 WL 467151, at *2 (N.D. Ill. Mar. 27, 2002) (holding that Baxter's withdrawal of plastic containers from its ANDA submission that would potentially infringe Abbott's 6,074,668 patent covering storage of sevoflurane in plastic containers made alleged infringement nonjusticiable).

Defendant next argues that the "immediacy" prong of the *Lang* test is not satisfied because the gap in time in this case from filing of the complaint to potential infringement is almost twenty-two months. The period of time between the date on which the complaint was filed and the date when potentially infringing activities will begin are

important under the "immediacy" element. *Sierra*, 363 F.3d at 1378-79. "The greater the length of this interim period, the more likely the case lacks the requisite immediacy." *Id.* at 1379. This time period is not an absolute factor, and "a court must examine the totality of the circumstances." *RDP Techs., Inc. v. N-Viro Int'l Corp.*, No. Civ. A. 00-697-RRM, 2001 WL 1083762, at *5 (D. Del. Sept. 17, 2001); *see also Lang*, 895 F.2d at 764 (comparing the "immediacy" element with that of the "reasonable apprehension" element of a patent declaratory action where the plaintiff is the threatened infringer); *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988) (noting that in a patent declaratory action where the plaintiff is the threatened infringer, the court must consider the "totality of the circumstances" in determining whether the defendant's conduct creates a reasonable apprehension that it will enforce its patent).

Defendant supports its argument with the holding in *Lang v. Pacific Marine and Supply Co.* that a nine-month delay between the filing of the complaint and the completion of the hull for a ship was not sufficient to meet the requirements of an "actual controversy." 895 F.2d at 764-65. However, the court noted "the accused infringers had not distributed sales literature, prepared to solicit orders, or engaged in any activity indicating that the ship would soon be ready for sea." *Id.* at 765.

Defendants' reliance on the specific holding in *Lang* is not convincing based on the facts of this case. *Lang* involved the construction of a ship, while the case at hand involves the packaging for a generic drug already approved by the FDA. The nine-month limit in *Lang* cannot be imposed on this case. The *Lang* court considered the fact that the accused infringers had not engaged in any marketing activity when discussing the nine-month limitation under the immediacy requirement. *Id.* In this case, Defendant is

prepared to sell generic sevoflurane after getting approval of an ANDA, and the nine-month limitation cannot therefore be applied.

Defendant also looks to *Sierra Applied Sciences, Inc. v. Advanced Energy Industries, Inc.* for support, where the Federal Circuit found that the "immediacy" requirement was not met in a case concerning a power supply. 363 F.3d at 1379. The court noted that the power supply at issue was not built and operational until about a year after the case was filed, exceeding the nine-month period from *Lang*. *Id.* The power supply was not even mentioned in interrogatories six months after the case was filed. *Id.* Moreover, there was no existing or draft advertising literature for the power supply. *Id.*

Again, reliance on the holding in *Sierra* based on those specific facts is unpersuasive in this case. *Sierra* involved a product still in the development stage, not even identified at the time of filing, while the issue in this case is a product that has already undergone testing and is prepared for the market. The Federal Circuit in *Sierra* also noted that marketing efforts had not been made by the potential future infringer in its analysis of the "immediacy" element, further distinguishing this case, as the time and cost involved in filing an ANDA indicate an intent to market generic sevoflurane.

Furthermore, as Plaintiffs cite, the Federal Circuit in *Novopharm* determined that jurisdiction existed where there was an approximate seventeen-month delay between filing of the suit and actual infringement. 110 F.3d at 1571. Glaxo sued Novopharm on July 22, 1994 seeking a declaratory judgment that Novopharm would infringe on a Glaxo patent if and when it imported the infringing product following approval of its ANDA. *Id.* at 1564. The court decided that the delay met the "immediacy" requirement because Novopharm had sent a letter indicating that it intended to market the infringing product

after December 5, 1995 (before expiration of Glaxo's patent), and that FDA approval of Novopharm's ANDA was imminent. *Id.* at 1571.

Plaintiffs also support their position by citing *Glaxo Group Ltd. v. Apotex, Inc.*, where the district court found that a thirteen to nineteen-month delay between the filing of the suit and infringement met the immediacy requirement of *Lang*. 130 F. Supp. 2d at 1008-09. Glaxo filed suit in September 2000 seeking a declaration that Apotex would infringe Glaxo's patent on an antibiotic as a result of Apotex's ANDA filing in April 2000. *Id.* at 1007-08. Approval of the ANDA would take anywhere from eighteen to twenty-four months, resulting in approval before the expiration of Glaxo's patent. *Id.* at 1007. Based on the ANDA filing, Apotex's refusal to reply to demand letters from Glaxo regarding potential infringement issues, and "the enormous amount of money at stake," the court concluded that Apotex would enter the market as soon as possible and that the "immediacy" element from *Lang* was satisfied. *Id.* at 1009.

The case at hand is much closer factually to *Novopharm* and *Apotex* than to *Lang* and *Sierra*. Defendant already has an *approved* ANDA, and has indicated an intention to market the product in December 2005, when the Plaintiffs' license will have expired per the arbitral award. Based on the totality of the circumstances, including the fact that in this case the ANDA is already approved and the arbitral award sets a definite date of infringement, the "immediacy" element of *Lang* is satisfied by the twenty-two-month delay from the filing of the complaint to potential infringement. The Court notes that this delay is acceptable based only on the specific facts of this case, and is not meant to extend the allowable time frame in other potential declaratory judgment cases in which the patentee seeks a declaration of infringement against a potential future infringer. This

Court denies Defendant's motion to dismiss for lack of subject matter jurisdiction.

Defendant has also moved, in the alternative, to stay this case pending the outcome of case no. 01 C 1867, which involves infringement of the '176 patent. Defendant claims that certain facts from case no. 01 C 1867 could have a collateral estoppel effect on issues in this case, and that invalidity, unenforceability and claim indefiniteness issues regarding the '176 patent will "most assuredly" place issues with respect to the '492 and '859 patents into "much sharper relief." These are weak arguments, at best, as issued patents are presumed valid per 28 U.S.C. § 282, regardless of the validity of related patents, and clear and convincing evidence is required to show otherwise. *See Dana Corp. v. Am. Axle & Mfg., Inc.*, 279 F.3d 1372, 1375 (Fed. Cir. 2002) (noting that presumption of patent validity can only be overcome by clear and convincing evidence); *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1379 (Fed. Cir. 1999) ("While evidence of invalidity regarding the claims of one patent may certainly apply to those of another, a party may not avoid its burden of proof by making a blanket statement that its proofs with respect to one patent apply to another and not provide a formal analysis as to why that is true.") The key issue in case no. 01 C 1867 is the "effective amount" terminology used in the '176 patent, which is not an issue in this case. The resolution of case no. 01 C 1867 will not necessarily resolve the issues involved here. Accordingly, the motion to stay is denied.

CONCLUSION

For the foregoing reasons, the Court denies Defendant's motion to dismiss for lack of subject matter jurisdiction and denies Defendant's alternative motion to stay this case pending the outcome of case no. 01 C 1867 [doc. nos. 9-1 and 9-2].

SO ORDERED **ENTERED:**

HON. RONALD A. GUZMAN
United States Judge

DATED: August 13, 2004